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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,972	10/21/2003	John H. Brekke	15871/124	4698

23595 7590 05/16/2007

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,972	BREKKE ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-24 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) ~~Paper No(s)~~/Mail Date 6/1/04; 7/8/04; 7/12/04; 7/30/04; 8/2/04; 8/3/04; 8/9/04; 8/24/04; and 9/20/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-40 ARE PRESENTED FOR EXAMINATION

Applicants' Response filed February 13, 2007 and Information Disclosure Statements filed June 1, 2004, July 8, 2004, July 12, 2004, July 30, 2004, August 2, 2004, August 3, 2004, August 9, 2004, August 26, 2004 and September 20, 2004 have been received and entered into the application. As reflected by the attached, completed copies of form PTO-1449, (10 sheets), the Examiner has considered the cited references.

Restriction Requirement

Applicants' election with traverse of the invention of Group II is acknowledged. The traversal is on the grounds that in searching for and examining the invention of Group II, a search for the invention of Group I, i.e., an implantable device, would also be required. This is not found persuasive because in searching for and considering the patentability of Group II, different considerations are necessary. Further, not all claims of Group I define an implantable device of the same scope as that employed in the invention of Group II. For example, compare present claim 1, where a single active agent and a single polymer is required, to the implant employed in the method of claim 25, i.e., where a first and second active agent are required and there is no express requirement for a polymer of any kind. Additionally, consideration of the patentability of an implantable device, per se, and a method involving the use of such a device are different. As an example, given the construct of present claim 1, an implantable device could be found which is not intended for the same use as recited, but would nevertheless be applicable, (*e.g.*, see MPEP § 2111.01(II)).

Finally, a situation where it is proper to find an invention directed to a composition/device patentably distinct from a method involving use of that device by showing that the method could be practiced with a materially different product is specifically addressed at MPEP § 806.05(h). Here, the Examiner has offered that the method as claimed could be practiced with a materially different product, such as a tablet or injectable preparation, (previous Office action, bridging pages 2-3). Applicants have not provided any argument, convincing or otherwise, that the alternative process advanced by the Examiner in the previous Office action could not be practiced. Accordingly, the Examiner's decision to restrict the claimed subject matter is proper.

Present claim 40 has been included in the non-elected subject matter because it is directed to a surgical method and thus is "unrelated" to the cancer method as provided for under MPEP § 802.1 and § 806.06, i.e., different effects are involved. The surgical method is also distinct from the implantable device for the same reasons as given for the cancer method in the previous Office action.

For the above reasons, the requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-24 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 25-39 are herein acted on the merits.

Applicants should note that the Examiner did provide for consideration of each of the inventions present in this application. In particular, had Applicants elected the implantable device, and the device was ultimately found to be allowable, the method claims then would be,

sua sponte, rejoined where the process claims either depended from the device claims or else required all of the limitations of the allowable device claims, (see the previous Office action beginning on page 4 under the heading "Rejoinder Notification").

Claim Objection

Claim 27 is objected to because at line 3, "replate" appears to be a misspelling of ---replicate---.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating breast, prostate and/or colon cancer, (see the specification at page 1, third paragraph), does not reasonably provide enablement for the treatment of "cancer", in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims and while possessing at least a reasonable expectation of success.

Suggestion for Overcoming the Present Rejection

Applicants may wish to consider amending the claims to include a Markush group reciting "one or more cancers selected from the group consisting of breast cancer, prostate cancer and colon cancer" The suggested language finds express support in the specification as originally filed at page 1, third paragraph and thus would not represent new matter.

Support for Rejection

In regards to the present rejection, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) Nature of invention;

2) State of the art;

3) Level of ordinary skill in the art;

4) Level of predictability in the art;

5) Amount of direction and guidance provided by the inventor;

6) Existence of working examples;

7) Breadth of claims; and

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) Nature of the invention.

The claims are directed to treating cancer in general.

2) State of the art.

While the state of the art is relatively high with regard to the treatment of specific cancer or tumor types, the state of the art with regard to treating cancer broadly is underdeveloped. In particular, there is no known anti-cancer or anti-tumor agent, or combinations thereof, that is effective against all cancer types. The Cecil reference (cited by Examiner on the attached form

PTO-892), clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent or agents that is effective for each and every type of cancer or tumor, which is the subject matter encompassed by the present claims, (see Cecil at page Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 10684 and Table 198-9 at page 1071).

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high and would include the skill possessed by a person holding a doctor of medicine degree. However, given the state of the art as set forth above, the artisan is currently unaware of any one particular anti-cancer or anti-tumor agent, or a combination thereof, that is effective in treating all known types of cancer or tumors.

4) Level of predictability in the art.

The lack of significant guidance from the present specification or prior art with regard to the treatment of all cancers or tumors in a patient with any known anti-cancer or anti-tumor formulation imparts a significant degree of unpredictability in practicing the invention as presently claimed.

5) Amount of direction and guidance provided by the inventor.

The guidance given by the specification is to generally administer the claimed active agent to treat cancers or tumors broadly and, more specifically, breast, prostate and/or colon cancer.

6) Existence of working examples.

There are no working examples provided in the specification of treating cancer of any type.

7) Breadth of claims.

The complex nature of the subject matter to which the present claims are directed is exacerbated by the breadth of the claim. The claims are extremely broad due to the vast number of possible cancer types represented by the term "cancer".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. Applicants have failed to provide guidance and information to allow the skilled artisan to ascertain that the present active agent is effective against all types of cancers or tumors. The limited enablement for the specifically named cancers/tumors is noted, but does not support all cancers or tumors as is being claimed.

Further Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that cancers of a non-restricted nature could each be successfully treated is doubted because the art (see Cecil, above) teaches that, at best,

that only certain cancer/tumors may be treated with only certain compounds or combinations thereof. Given this, the treatment of all known cancers is merely a possibility and not a treatment outcome that could be accomplished with a reasonable degree of certainty or without a burden of undue experimentation, i.e., determining for which cancers/tumors the claimed formulation could treat.

Summary

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicants would not imbue the skilled artisan with a reasonable expectation that cancers/tumors of all types could be effectively treated with the presently claimed formulations. In order to actually achieve the claimed objective, if at all possible, it is clear from the discussion above that the skilled artisan could not rely on Applicants' disclosure as required by 35 U.S.C. § 112, first paragraph in light of the state of the art. Given that the art fails to recognize and Applicant has failed to demonstrate that all known cancers/tumors could actually be treated, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention.

Accordingly, claims 25-39 are deemed properly rejected.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-39 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps/elements, such omission amounting to a gap between the steps. See

MPEP § 2172.01. The omitted step/element is the presence of a cancer condition and an actual step where it is required that the cancer is treated. Also, while the claims require a wound, there is no antecedent basis of a host in whom such a wound is present.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 10, 2007